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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,530	11/13/2003	Andrew Thomas Forsberg	47563.0014	9304
7590 03/27/2008				
L. Grant Foster HOLLAND & HART LLP 555 - 17th Street, Suite 3200 P.O. Box 8749 Denver, CO 80201			EXAMINER GETTMAN, CHRISTINA DANIELLE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 03/27/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/713,530

**Applicant(s)**

FORSBERG ET AL.

**Examiner**

CHRISTINA D. GETTMAN

**Art Unit**

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 5, 7, 12-16, 20-22, 24, 25, 28-39 and 45-60 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 7, 12, 22, 24, 25 and 31-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 13-16, 20-21, 28-30, 45-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (U.S. Patent No. 6,179,863). Kensey discloses a device that includes an insertion sheath (ref. 28), a dilator (ref. 300 and ref. 400), a port on the sheath (ref. 304), a port on the dilator (ref. 404), the dilator extending beyond the distal end of the sheath (see Fig. 27 and Fig. 29), and each of the ports being in fluid communication with a proximal end of the device. The more proximal hole can be used as an over-insertion hole since it would be located at a proximal point to the first hole. This would allow the user to know that the device has been inserted too far. Each of the holes is associated with a lumen that goes through the device up to the proximal end of the device. Since the device is inserted into the insertion sheath, both of the ports are associated with a lumen in the insertion sheath and dilator.

Claims 1, 13-16, 20-21, 28-30, and 45-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginn (U.S. Patent No. 6,626,918). Ginn discloses a device having an insertion sheath and a dilator. The distal end of the dilator extends beyond a distal end of the insertion sheath. As shown in fig. 10-14, both the dilator and the sheath have a plurality of distal bleed-back ports which communicate with lumens

leading to indicator ports at the proximal end. Depending on which ports are selected, the ports can be both circumferentially and longitudinally spaced from each other. The proximal-most port would serve to indicate that an over-insertion has occurred. See col. 8 line 7-col. 9 line 61. There is a port located in the distal end of the dilator and in the distal end of the sheath. As shown in Figs 14A-14B, the more distal port is used as the initial insertion bleed-back port while the more proximal one is used as an over-insertion port. It would be obvious to move the distal port past the distal end of the insertion sheath to indicate that the device, beyond the insertion sheath, was located in the vessel. Moving the port would not obtain unexpected results and, therefore, is obvious.

#### ***Response to Arguments***

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ginn et al. (U.S. Patent No. 2004/0073255), Kanner et al. (U.S. Patent No. 2002/0151921), and Ashby (U.S. Patent No. 7,025,748) disclose the use of indicators in the distal end of a sheath and/or dilator to allow the user to determine the depth of the device.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA D. GETTMAN whose telephone number is (571)272-3128. The examiner can normally be reached on Monday-Thursday 6:45 am to 4:30 pm (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

/Christina D Gettman/  
Examiner, Art Unit 3734  
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